

Oaks, Brian

From: Oaks, Brian
Sent: Monday, February 25, 2002 4:07 PM
To: 'biocore1@aol.com'
Subject: Patent Application



Patent Application
Orthofix VE...



Assignment.DOC



Declaration &
POA.DOC

e: Stimulating Cell Receptor Activity Using Electromagnetic Fields
Our File No.: 090928.A170

Dear Mr. Fitzsimmons:

Enclosed is the above-identified patent application as filed on February 22, 2002, along with a set of documents for your signature. Please review the application as soon as possible to confirm that it accurately and adequately describes the invention and the best mode of practicing the invention. After you have completed your review, please execute the "Declaration and Power of Attorney" and "Assignment" documents, signing your name exactly as it is typewritten in blue ink and dating each document (note that the Assignment document should be dated twice, once with the date the Assignment document is executed and once with the date the Declaration and Power of Attorney document is executed, usually the same date).

Please note again that at the time the application is executed, you will be acknowledging your duty to disclose material prior art to the PTO. Failure to disclose material prior art may invalidate any patent issuing on the application. If you know of any of the following, please let me know:

1. Written materials, such as patents, technical articles, or product brochures that predate the filing of the present application;
2. Information concerning public disclosure or public use that predates the filing of the present application;
3. Information disclosed to third parties without confidentiality restrictions on its disclosure that predates the filing of the present application; and
4. Information concerning sales or offers for sale of systems or methods related to your invention that predate the filing of the present application.

After these documents have been fully executed, please return the signed documents to me in the enclosed Federal Express envelope so that I can file them with the PTO.

If any of you have questions, please let me know.

Very truly yours,

Brian W. Oaks

BWO/mc
Attachments

Brian W. Oaks
214.953.6986
Fax 214.661.4986
brian.oaks@bakerbotts.com

g

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April 18, 2002

Brian W. Oaks
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brian.oaks@bakerbotts.com

**PRIVILEGED AND CONFIDENTIAL
ATTORNEY-CLIENT COMMUNICATION**

VIA CERTIFIED MAIL
#7001 1140 0000 7421 2110

Robert J. Fitzsimmons, Ph.D.
1700 Encanto Lane
Colton, CA 92324

Re: *Stimulating Cell Receptor Activity Using Electromagnetic Fields*
Our File No.: 090928.A170

Dear Mr. Fitzsimmons:

This letter is a follow-up to my previous letter of February 25, 2002. As with that letter, enclosed with this letter is the above-identified patent application as filed on February 22, 2002, along with a set of documents for your signature.

I have enclosed a copy of the Research Agreement executed by you and Orthofix. Please note Sections 5.02 in which you have agreed to "fully cooperate and provide diligent assistance to Orthofix, its agents and its patent attorney, without additional compensation," so that patent applications covering technology such as that covered in the above-identified patent application may be drafted and prosecuted. You should also note Section 5.03 in which you have specifically agreed to "execute all papers necessary to file, prosecute and procure Orthofix's rights in any patent applications or patents" covering such technology without additional compensation for your time and assistance. You should be aware that the enclosed "Declaration and Power of Attorney" is a paper "necessary to file, prosecute and procure" the above-identified patent application.

In accordance with this Agreement, please review the application as soon as possible to confirm that it accurately and adequately describes the invention and the best mode of practicing the invention. After you have completed your review, please execute the "Declaration and Power of Attorney" and "Assignment" documents, signing your name exactly as it is typewritten in blue ink and dating each document (note that the Assignment document should be dated **twice**, once with the date the Assignment document is executed and once with the date the Declaration and Power of Attorney document is executed, usually the same date). If any changes to the application are necessary or if you have any questions, please call me before signing the documents.

April 18, 2002

Please note again that at the time the application is executed, you will be acknowledging your duty to disclose material prior art to the PTO. Failure to disclose material prior art may invalidate any patent issuing on the application. If you know of any of the following, please let me know:

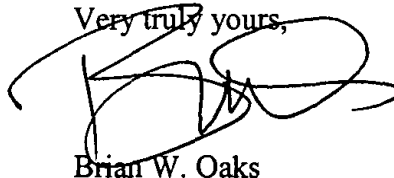
1. Written materials, such as patents, technical articles, or product brochures that predate the filing of the present application;
2. Information concerning public disclosure or public use that predates the filing of the present application;
3. Information disclosed to third parties without confidentiality restrictions on its disclosure that predates the filing of the present application; and
4. Information concerning sales or offers for sale of systems or methods related to your invention that predate the filing of the present application.

After these documents have been fully executed, please return the signed documents to me in the enclosed Federal Express envelope so that I can file them with the PTO.

If you choose not to review the application and sign the enclosed papers, I would at least appreciate your indication of your unwillingness to do by your signature below, so that Orthofix may consider its alternatives.

If any of you have questions, please let me know.

Very truly yours,



Brian W. Oaks

BWO/mc
Attachments

Although I have received this letter, the enclosed patent application, and the related filing documents, I am unwilling to review and/or execute the documents enclosed with this letter.

Robert J. Fitzsimmons

Date

RESEARCH AGREEMENT
BETWEEN
ORTHOFIX, INC.
AND
ROBERT J. FITZSIMMONS, Ph.D.

RESEARCH AGREEMENT

THIS RESEARCH AGREEMENT (this "Agreement") is made and entered into as of January 15, 1999 (the "Effective Date"), by and between Orthofix, Inc., a corporation organized under the laws of the State of Minnesota, with its principal place of business at 250 E. Arapaho Road, Richardson, Texas 75081 (hereinafter "Orthofix"), and Robert J. Fitzsimmons, Ph.D., an individual residing in the State of California at 32151 Bonview Drive, Mentone, California 92359 and having a mailing address of P.O. Box 187, Mentone, California 92359 (hereinafter "Fitzsimmons").

RECITALS

WHEREAS, Orthofix desires to support research in the application of electromagnetic fields to biological systems, including theories, models and principles on how electromagnetic fields act on a specific biological pathway;

WHEREAS, Fitzsimmons has certain knowledge, training, expertise and intellectual property in the application of electromagnetic fields to biological systems, including theories, models and principles on how electromagnetic fields act on a specific biological pathway, and in performing research in such application of electromagnetic fields to biological systems;

WHEREAS, Fitzsimmons desires to obtain research funds to purchase laboratory and scientific equipment and to conduct additional research in the application of electromagnetic fields to biological systems, including theories, models and principles on how electromagnetic fields act on a specific biological pathway;

WHEREAS, pursuant to the terms of this Agreement, Orthofix agrees to provide certain research funds to Fitzsimmons through a funding commitment in exchange for Fitzsimmons' knowledge, training, expertise, technical information and research in the application of electromagnetic fields to biological systems, including theories, models and principles on how electromagnetic fields act on a specific biological pathway, that is owned or developed by Fitzsimmons; and

WHEREAS, pursuant to the terms of this Agreement, Fitzsimmons agrees to provide Orthofix with the rights to any intellectual property that may result as an outcome of this Research Agreement. If this intellectual property has commercial product potential, Orthofix and Fitzsimmons agree to enter into a separate product development and royalty agreement for each potential product outcome.

NOW, THEREFORE, in consideration of the mutual covenants and undertakings herein contained, the parties agree as follows:

ARTICLE I
DEFINITIONS

1.00 Terms in this Agreement, other than Article headings, that are set forth in uppercase letters have the meanings established for such terms in the succeeding paragraphs of this Article.

1.01 INTELLECTUAL PROPERTY shall include, without limitation, ideas, concepts, expressions, designs, industrial designs, drawings, specifications, copyrights, trademarks, service marks, logos, trade names, trade dress, patents and patent applications, including any provisional, continuations, continuations-in-part, divisional, reissues, reexaminations, extensions, foreign or international counterparts, equivalents or related to such patents or patent applications, invention disclosures, inventions, whether patentable or not, developments, discoveries, unpublished research, trade secrets, know-how, methods, techniques, skill, knowledge, experience, data, technical data, software and any other proprietary rights conceived, whether recorded in a tangible form or not, or reduced to practice.

1.02 TECHNOLOGY shall mean all INTELLECTUAL PROPERTY related in any manner to the application of electromagnetic fields to biological systems, that includes, without limitation, theories, models, research and principles on how electromagnetic fields and signals act on a specific biological pathway, and any related methods, processes, procedures, devices, products, components, and the like.

1.03 IMPROVEMENTS shall mean any and all INTELLECTUAL PROPERTY related in any manner to any developments, modifications, enhancements, advances, research and the like to the TECHNOLOGY.

1.04 ASSIGNED PATENTS shall mean issued patents assigned to Orthofix under this Agreement that have not been adjudged to be invalid or unenforceable, and that are not being currently challenged in a court as being invalid or unenforceable. The patents assigned to Orthofix may include, without limitation, patents that name Fitzsimmons as an inventor or a joint inventor and those that Fitzsimmons has an ownership interest.

1.05 ORTHOFIX PROPRIETARY INFORMATION shall mean any confidential information that (i) is identified as confidential or proprietary to Orthofix, or by its nature is obviously confidential or proprietary to Orthofix, and includes, without limitation, information that relates to Orthofix or its customers, past, present or future research and development, business affairs, products, services, materials, systems, procedures or methodologies, and (ii) is discovered, observed or communicated to Fitzsimmons in connection with the negotiation, preparation or performance of this Agreement and includes, without limitation, ideas, concepts, expressions, know-how, trade secrets, methods, techniques, skill, knowledge, experience and INTELLECTUAL PROPERTY.

1.06 RESEARCH FUNDING shall mean funding provided to Fitzsimmons under this Agreement.

1.07 The definitions of this Article may be used in the singular or plural when the context so requires.

1.08 Orthofix and Fitzsimmons are hereunder commonly referred together as "parties" and individually as "party".

ARTICLE II

SCOPE OF RESEARCH AND OBLIGATIONS

2.00 Fitzsimmons agrees to establish a cell culture laboratory and to professionally and competently conduct scientific research during the term of this Agreement in the application of electromagnetic fields to biological systems, specifically including theories, models and principles on how electromagnetic fields act on specific biological pathways and cells and in identifying specific electromagnetic signals and pulses, including frequencies, frequency ranges, and waveform characteristics, that act on specific biological pathways and cells. Fitzsimmons agrees that such research shall be conducted using the highest scientific standards, conduct, ethics and best practices, and in accordance with such requirements as may be prescribed by Orthofix from time-to-time.

2.01 Fitzsimmons agrees to focus the research described in Section 2.00 as requested by Orthofix in writing.

2.02 Orthofix requests Fitzsimmons to focus the research described in Section 2.00 towards finding specific electromagnetic signals that may be used as potential treatments for osteoporosis. At a minimum, Fitzsimmons shall, after establishing the cell culture laboratory, determine sine wave frequencies of electromagnetic fields for stimulating bone cells, test various pulse parameters of electromagnetic fields for stimulating bone cells.

2.03 Fitzsimmons agrees to provide a monthly scientific report to Orthofix within two weeks after the end of each calendar month that detail, among other things, the research performed, data gathered, and results concluded for the calendar month.

2.04 Fitzsimmons agrees to promptly provide to Orthofix written invention disclosures detailing the INTELLECTUAL PROPERTY in the TECHNOLOGY and the IMPROVEMENTS developed during the term of this Agreement.

2.05 Fitzsimmons agrees to perform consultation and such other research as may be requested by Orthofix from time-to-time while receiving RESEARCH FUNDING.

2.06 Fitzsimmons agrees to personally perform all research under this Agreement and to dedicate his efforts and energy towards performing under this Agreement. Fitzsimmons agrees not to accept or perform research sponsored by a third party during this agreement unless agreed in writing by Orthofix.

2.07 Fitzsimmons agrees not to hire any additional personnel, including, without limitation, employees, consultants, assistants, technicians scientists and other researchers, to assist him with his research obligations hereunder, unless given prior written approval by Orthofix. If Orthofix consents to additional personnel, Fitzsimmons agrees that any such personnel must execute and be obligated by an employment agreement or non-disclosure agreement that has been pre-approved in writing by Orthofix as an agreement that is suitable for use in connection with this Section.

2.08 Fitzsimmons agrees not to publish, discuss, or disclose to third parties, in any manner whatsoever, any aspect of the research performed and the results obtained under this Agreement, including the contents of this Agreement, during the term of this Agreement and extending one year thereafter unless prior approval is obtained from Orthofix.

2.09 Fitzsimmons agrees not to publish, discuss, or disclose to third parties, in any manner whatsoever, any INTELLECTUAL PROPERTY in the TECHNOLOGY and the IMPROVEMENTS, unless Orthofix, in its exclusive discretion, provides a written release to Fitzsimmons. Fitzsimmons' obligation under this Section continues until RESEARCH FUNDING has ceased.

2.10 Fitzsimmons agrees to fully perform and extend the term of this Agreement when Orthofix elects under an option to extend the term of this Agreement for another period.

2.11 Orthofix agrees to enter into a Product Development Agreement with Fitzsimmons which covers any INTELLECTUAL PROPERTY in the TECHNOLOGY and the IMPROVEMENTS that are developed as part of this research agreement.

ARTICLE III

FUNDING

REDACTED

ARTICLE IV

ASSIGNMENT OF INTELLECTUAL PROPERTY

4.00 Fitzsimmons and Orthofix will have complete right, title and interest in all INTELLECTUAL PROPERTY in the TECHNOLOGY and the IMPROVEMENTS, that are developed as part of this research agreement.

4.01 Orthofix shall have the absolute right to assign, license, sub-license and otherwise exploit or dispose of the INTELLECTUAL PROPERTY in the TECHNOLOGY assigned herein.

4.02 Fitzsimmons agrees not to assign his right, title or interest in all INTELLECTUAL PROPERTY in the TECHNOLOGY and the IMPROVEMENTS to any third parties. Fitzsimmons' obligation under this Section continues indefinitely, even though RESEARCH FUNDING has ceased except as stated in Section 4.03.

4.03 If Orthofix does not act enter into a Product Development Agreement covering the Intellectual Property in the Technology and the Improvements or fails to meet the conditions of a Product Development Agreement, Fitzsimmons will be free to assign, license, sub-license and otherwise exploit the INTELLECTUAL PROPERTY in the TECHNOLOGY assigned herein.

ARTICLE V

PATENT FILINGS AND MAINTENANCE

5.00 As an outcome of the research conducted under this agreement, Orthofix shall pay all fees and costs, including legal fees, associated with the filing of both domestic and foreign patent applications covering the INTELLECTUAL PROPERTY in the TECHNOLOGY and the IMPROVEMENTS. Orthofix shall have the exclusive right and absolute discretion to determine which of inventions of the INTELLECTUAL PROPERTY in the TECHNOLOGY and the IMPROVEMENTS should be pursued as patent applications, in which countries such patent applications should be pursued, and in any and all decisions and strategy related to prosecution of such patent applications. Fitzsimmons shall not challenge Orthofix's decisions and discretion exercised with respect to such patent applications and shall have no remedy or recourse related to Orthofix's decisions and discretion.

5.01 Orthofix shall pay all maintenance fees, annuities, annuity taxes, taxes and the like to maintain such patents owned by Orthofix. However, Orthofix shall have the exclusive right and absolute discretion in determining which of the patents are of sufficient value to be maintained by the payment of such maintenance fees, annuities, annuity taxes, taxes and the like.

5.02 Fitzsimmons shall fully cooperate and provide diligent assistance to Orthofix, its agents and its patent attorney, without any additional compensation, so that patent applications covering inventions of the INTELLECTUAL PROPERTY in the TECHNOLOGY and the IMPROVEMENTS may be drafted and prosecuted. However, Orthofix shall compensate Fitzsimmons for any travel and lodging expenses that have been pre-approved in writing by Orthofix and not contemplated by any RESEARCH FUNDING provided by Orthofix to Fitzsimmons. Fitzsimmons' obligation under this Section, among others, continues indefinitely, even though RESEARCH FUNDING has ceased.

5.03 Fitzsimmons shall execute all papers necessary to file, prosecute and procure Orthofix's rights in any patent applications or patents covering an invention of the INTELLECTUAL PROPERTY in the TECHNOLOGY and the IMPROVEMENTS without additional compensation for Fitzsimmons' time and assistance. However, Orthofix shall compensate Fitzsimmons for any travel and lodging expenses that have been pre-approved in writing by Orthofix and not contemplated by any RESEARCH FUNDING provided by Orthofix to Fitzsimmons. Fitzsimmons' obligation under this Section, among others, continues indefinitely, even though RESEARCH FUNDING has ceased.

5.04 Orthofix shall no longer be obligated under Sections 5.00 and 5.01 in the event that Orthofix forfeits its right, title and interest in the INTELLECTUAL PROPERTY in the TECHNOLOGY and the IMPROVEMENTS to Fitzsimmons.

ARTICLE VI

REPRESENTATIONS AND WARRANTIES BY FITZSIMMONS

REDACTED

REDACTED

ARTICLE VII
REPRESENTATIONS AND WARRANTIES BY ORTHOFIX

REDACTED

ARTICLE VIII
(Indemnification)

REDACTED

ARTICLE IX
(INDEPENDENT CONTRACTOR / INSURANCE)

REDACTED

ARTICLE X
(TERM / TERMINATION)

10.00 The term of this Agreement corresponds to the Effective Date of the Agreement and extends for the period of one year. Except as noted herein, when the term of this Agreement ends, the only obligations to the other party under this Agreement that immediately cease are Orthofix's obligation to provide RESEARCH FUNDING to Fitzsimmons for the current PHASE and Fitzsimmons' obligation to conduct additional research.

10.01 Either party may terminate this Agreement without cause by notifying the other party in writing at least 30 days ahead of the termination.

ARTICLE XI
(CONFIDENTIAL INFORMATION)

REDACTED

ARTICLE XII
(MISCELLANEOUS PROVISIONS)

REDACTED

REDACTED

REDACTED

REDACTED

IN WITNESS WHEREOF, each of the parties hereto has caused this Agreement to be executed in duplicate originals by their duly-authorized representatives.

Orthofix, Inc.

By: Charles J. Dillman

Date: 2/3/99

Name: Charles J. Dillman, Ph.D.

Title: Group Vice President, Research & Development

Robert J. Fitzsimmons, Ph.D.

By: Robert J. Fitzsimmons

Date: 2-26-99

Name: Robert J. Fitzsimmons, Ph.D.

Title: An individual



February 2, 2000

Bob Fitzsimmons, Ph.D.
BioCore Technologies
24769 Redlands Blvd, Suite E
Loma Linda, CA 92354

Dear Dr. Fitzsimmons:

Orthofix, Inc., has decided to continue your contract, "Research Agreement", for another year starting at the annual "effective date" of January 15, 2000, and terminating one year later (unless renewed under terms of contract) January 14, 2001. We look forward to our continued partnership and the development of a novel PEMF product in 2000.

Sincerely


ORTHOFIX INC.


Charles J. Dillman, Ph.D.

Print Name
Charles J. Dillman

Title: Crp VP of R&D
Date: 2/02/2000

If agree:


Robert J. Fitzsimmons, Ph.D.

Print Name
Robert J. Fitzsimmons

Title: Individual
Date: 02/09/2000

Orthofix Inc.
The Storrs Building
Huntersville Business Park
10115 Kincey Avenue
Suite 250
Huntersville, NC 28078
704.948.2600